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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/444,459

Applicant(s)

Cameron et al

Examiner

Louise Leary

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-25 is/are allowed.
- 6) ☒ Claim(s) 1-20, 26-29, 32, 33, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: CL

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1. Claims 1-33 and 55 are pending in this application.

Claims 34-54 have been canceled per applicant's instructions in the amendment filed August 1, 2001.

2. The rejection of claims 1-20, 26-29, 32-33 and 55 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U. S. C. 103(a) as obvious over Cook (US Patent 3,928,594) has been maintained for reasons of record.

3. *NEW GROUNDS OF REJECTION:*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of diagnosing pain, does not reasonably provide enablement for "the presence of lesions, burns, skeletal fractures, inflammation, or other traumatic insults in a patient". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to diagnose pain for the presence of lesions, burns, skeletal fractures, inflammation, or other traumatic insults in a patient, the invention commensurate in scope with these claims. The specification is enabling for pain diagnosis associated with a marker rather than

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the presence of lesions, burns, skeletal fractures, inflammation, or other traumatic insults in a patient.

4. Applicant's arguments filed August 1, 2001 have been fully considered but they are not persuasive.

At page 6 of the amendment applicant's have argued "...neither the independent claims 1, 9, 16, 21, 26 and 29 nor the dependent claims 2-8, 10-15, 17-20, 21-25, 27-28 and 30-33, all of which deal with methods of diagnosing pain or stress in patients by determining the amount of a marker or markers in a biological sample or samples obtained from said patients wherein said marker or markers correlate with the perception of pain or stress, are anticipated by either Cook or Yang et al., and therefore respectfully request that rejections of claims 1-33 on the basis of 35 U.S.C. 102(b) be withdrawn." in regards to the rejection of the claims under 35 U.S.C. 102(b). In regards to the rejection of the claims under 35 U.S.C. 103(a) applicants have argued "...neither the independent claims 1, 9, 16, 21, 26 and 29 nor the dependent claims 2-8, 10-15, 17-20, 21-25, 27-28 and 30-33, are obvious from either Cook or Yang et al., and therefore respectfully request that rejections of claims 1-33 on the basis of 35 U.S.C. 103(a) be withdrawn." at page 9 of the amendment.

The examiner has carefully considered applicants' arguments and submissions. Claims 1-20, 26-29, 32-33 and 55 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35

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U. S. C. 103(a) as obvious over Cook (US Patent 3,928,594) has been maintained for reasons of record. It is noted that Cook discloses a method of diagnosing the intensity of pain in a patient comprising determining the amount of cholinesterase in a biological sample from the patient. Cook discloses methods of diagnosing the intensity of a pain perceived by a patient comprising determining the amount of neurotransmitter or cholinesterase, pharmaceutical compositions and methods for treating patients with pathological central nervous system (i.e., brain and spine) or spinal cord conditions which anticipates or renders obvious the present invention. The burden of proof is on applicant to show patentably distinct differences between the invention claimed and the subject matter disclosed by the Cook disclosure.

The Yang et al reference was cited to further show the state of the art since a method for diagnosing pain in a patient and evaluating patients injected with acetylcholinesterase inhibitor was disclosed.

For these reasons the rejection of claims 1-20, 26-29, 32-33 and 55 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U. S. C. 103(a) as obvious over Cook (US Patent 3,928,594) has been maintained.

5. Claims 21-25 are allowable over the prior art of record.

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6. Claims 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


LOUISE N. LEARY
PRIMARY EXAMINER

October 9, 2001